UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re Biogen Idec, Inc. Securities Litigation	X : : : : : X	Civil Action No. 05-cv-10400 (RCL) CLASS ACTION

PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' REVISED MOTION TO DISMISS THE CONSOLIDATED CLASS ACTION COMPLAINT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

OTHER SOURCES

PRELIMINARY STATEMENT

This action is based upon serious misstatements and omissions of material fact by the Defendants herein concerning the purported safety and market share of Tysabri, a drug that was critical to Biogen's continued growth and ability to access an expanded market of patients afflicted by multiple sclerosis ("MS"), Crohn's Disease ("Crohn's") and Rheumatoid Arthritis. ¶ 69. Throughout the Class Period,[1] Defendants issued a series of misstatements of material fact, which aggressively represented to investors that Tysabri would "capture the lion's share of the [$4 billion] MS market" and that the drug met the market's "needs with a new way to fight MS. . . with a good tolerability and safety profile." ¶¶ 234-35, 282-83.[2]

As investors would ultimately learn, Defendants' Class Period statements were materially false and misleading because, among other reasons, Defendants failed to disclose that: (i) Tysabri was a highly dangerous drug that severely suppressed the immune system and had already caused the ***deaths*** of patients taking the drug during its clinical trials; (ii) other patients taking the drug had developed ***life-threatening opportunistic infections,*** which are otherwise extremely rare and only occur in patients with severely compromised immune systems; and (iii) due to Tysabri's substantial risks, the drug was never an appropriate treatment for the expansive market the Defendants had represented. ¶¶ 133, 172.

Defendants admitted during an FDA Advisory Committee hearing on March 7-8, 2006 (the "March 2006 FDA Hearing") that they were aware of numerous opportunistic infections indicative of severe immunosuppression that had occurred in patients taking Tysabri during the drug's clinical trials and that such infections had caused the deaths of patients participating in

---

[1] February 18, 2004 through February 28, 2005, inclusive.

[2] References to "¶__" and "¶¶__" are to paragraphs of the Consolidated Class Action Complaint ("Complaint" or "Compl.").

such trials, even prior to Defendants' application to the FDA for approval of the drug. ¶ 132-40. However, Defendants failed to disclose such infections and deaths to the FDA or investors. As a result, Defendants were able to obtain "fast-track" approval of Tysabri, allowing them to accelerate the introduction of the drug to the broadest possible market. ¶ 223.

Defendants were ultimately forced to withdraw Tysabri from the market on February 28, 2005, after it was reported that an additional patient taking Tysabri had died from an opportunistic infection, Progressive Multifocal Leukoencephalopathy ("PML"),[3] which is also directly linked to severe immunosuppression. ¶ 330, Compl., n.3. Defendants further revealed that another patient in the clinical trials had also contracted PML as a result of the drug's severe immunosuppressive effects. Defendants subsequently admitted that these two patients ***had actually begun exhibiting signs and symptoms of PML as early as October 2004***. ¶ 322.

Following the withdrawal of Tysabri from the market, the price of Biogen common shares declined dramatically, ***erasing approximately $9.6 billion dollars in shareholder value*** and causing the Class to suffer enormous damages. ¶ 16. Also in response to the announcements on February 28, 2005, Defendants became ***the subject of an ongoing investigation by the Securities and Exchange Commission ("SEC")*** into "whether any violations of the federal securities laws occurred in connection with the suspension of marketing and commercial distribution of Tysabri." The SEC investigation ***continues to probe*** the Defendants' lack of disclosure to investors concerning the life-threatening effects of Tysabri and its extremely limited marketability.

[3] PML is an almost always ***fatal disease*** of the central nervous system ("CNS") specifically associated with severe immunosuppression typically contracted by persons with Acquired Immune Deficiency Syndrome ("AIDS"). Compl., n. 3.

As a result of their false and misleading statements, Defendants were able to ***personally profit*** from the artificial inflation of Biogen common shares, through substantial and unlawful insider selling. In particular, Defendant Thomas Bucknum, Executive Vice President and General Counsel of Biogen, ***sold 89,700 shares of Biogen stock, reaping approximately $1.9 million*** in proceeds from such sale on February 18, 2005. ¶¶ 391, 394. Defendant Bucknum executed this sale after learning that day at a meeting with other Biogen senior officers that a patient participating in the Tysabri clinical trials had been diagnosed with PML. ¶ 339. Based upon Defendant Bucknum's insider selling, the SEC filed a settlement enforcement action complaint (the "SEC Complaint") against him and subsequently announced that it had ***entered into a settlement agreement with Bucknum to pay $3 million in disgorgement, interest and penalties and prohibiting Bucknum from serving as an officer or director of a public company for five years***. ¶ 340. On March 9, 2005, Biogen announced that Defendant Bucknum had "resigned from the company" as a result of insider trading allegations. ¶ 339.

In addition to Defendant Bucknum, the Individual Defendants, themselves, sold approximately ***1,393,515 shares*** of Biogen stock during the Class Period for proceeds of approximately ***$84,212,688***. ¶ 387. Moreover, only eleven days before Defendants withdrew Tysabri from the market, each of the Individual Defendants received bonuses of as much as 140% of their annual compensation, based largely upon the Company's purported financial performance and product development. ¶¶ 397-401. These allegations, alone, are more than sufficient to create a strong inference of scienter and demonstrate that, despite Defendants' contentions, this case is not based upon "fraud by hindsight."

On June 5, 2006, the FDA announced that it had approved a limited return of Tysabri to the market for treating MS, but recommended that Tysabri ***only*** be used as a ***last resort therapy***

for MS patients in which no other therapy was tolerable or effective due to the dangers associated with the drug. ¶ 359. Not surprisingly, the FDA imposed landmark restrictive protocols, which now serve to severely limit usage. ¶¶ 360-64. In this regard, the FDA required Defendants to include a new "***black-box***" warning, its strictest warning, on the Tysabri label, which provides explicit warnings about specific opportunistic infections. Several of these infections, which were not reflected on the original Tysabri label, are ***the very same infections that caused the deaths of patients taking Tysabri during the clinical trials which Defendants failed to disclose during the Class Period***. ¶ 363.

Defendants' Memorandum is replete with misstatements of the Complaint's allegations and attempts to narrow the case by characterizing the Complaint as solely alleging Defendants' failure to promptly report cases of PML. In this regard, the Defendants fail to recognize that Plaintiffs' Complaint pleads a much broader scheme to defraud, designed by the Defendants to conceal during the Class Period the severe immunosuppressive effects of Tysabri, as well as the deaths and life-threatening infections resulting from the drug, in order to capitalize on its potential revenues.[4]

Defendants' Memorandum can be reduced to two unavailing arguments -- (i) that the Complaint does not allege particularized facts demonstrating that Defendants knew that Tysabri ***caused*** the opportunistic infection, PML; and (ii) the Complaint fails to specify ***when*** Defendants knew that Tysabri caused PML. *See* Defs.' Mem. 15. Defendants are wrong on both counts. Not only does the Complaint provide particularized facts demonstrating that, prior to and during the Class Period, Defendants knew that Tysabri caused PML, but it also establishes that Defendants knew Tysabri caused ***many additional*** opportunistic infections in patients taking

[4] *See* Defendants' Revised Motion to Dismiss the Consolidated Class Action Complaint for Violations of the Federal Securities Laws ("Defs.' Mem." or "Memorandum") 2.

Tysabri, and that certain patients had actually ***died*** from these infections during the drug's clinical trials. Thus, the Complaint more than adequately satisfies the applicable pleading standards under the PSLRA and Rule 9(b), and clearly establishes the Defendants' violations of the federal securities laws.

For these reasons set forth herein, the Court should deny Defendants' Motion to Dismiss.

STATEMENT OF FACTS

A. The Tysabri Clinical Trials

Tysabri was invented in the early 1990's by Dr. Lawrence Steinman and Dr. Ted Yednock, who subsequently ***abandoned further development of the drug*** in 1992, after their studies of Tysabri demonstrated that it was highly dangerous because it severely suppressed the immune system. ¶¶ 64-67. Thus, they concluded that Tysabri would cause patients on the drug to be vulnerable to serious, potentially life-threatening opportunistic infections. ¶ 64. Despite these findings, Defendants proceeded with clinical trials of Tysabri from 1995 through 2004 for the treatment of MS, Crohn's and Rheumatoid Arthritis, in order to take advantage of the drug's potential revenues and secure a greater market share. ¶¶ 87-93.

Each of the clinical trials consisted of three phases, which were conducted pursuant to a Collaboration Agreement between Biogen and Elan. ¶¶ 68-79. Pursuant to the Collaboration Agreement, Defendants were charged with approving and closely monitoring the progress of the drug, including tracking all adverse events. *Id.* The Collaboration Agreement further required both Biogen and Elan to keep the other informed of all developments affecting Tysabri, including adverse events. *Id.* In this regard, the Collaboration Agreement required Defendant Mullen and Elan's CEO, Kelly Martin, to meet regularly to discuss the progress of Tysabri and any important issues that arose. ¶ 76. Indeed, Defendant Mullen confirmed that during the

clinical trials, "Kelly Martin and [Defendant Mullen were] in frequent communications" to discuss the progress and issues concerning Tysabri. *Id.*

Upon completion of each phase of the clinical trials, the trial data was unblinded and Defendants were aware of their results by at least the following dates: (i) Phase I of the MS trials by 1995 (¶ 87); (ii) Phase II of the MS trials by September 2001 (¶ 88); (iii) Phase II of Crohn's trials by May 23, 2001 (¶ 91); (iv) Phase III of the Crohn's ENACT-1 study by July 24, 2003 (¶ 91); (v) Phase III of the ENACT-2 study by January 29, 2004 (¶ 92); and (vi) the first year of Phase III of the MS trials by February 18, 2004. ¶ 90.

As Plaintiffs allege, by February 2004, Defendants were aware of material levels of the Tysabri clinical trial data, particularly all incidents of death and opportunistic infections that occurred during those trials and which obviously threatened Tysabri's prospects, prior to applying to the FDA for fast-track approval. ¶ 95.

B. Defendants' Materially False And Misleading Statements

Throughout the Class Period, Defendants made materially false and misleading statements concerning the purported safety and marketability of Tysabri. For example, and without repeating the voluminous press releases and SEC filings identified in Plaintiffs' Complaint, Defendants falsely represented that the success of the Tysabri clinical trials "***further enhances the Company's confidence in its ability to achieve . . . previously stated earnings and revenue goals***" of approximately "15 percent top line and 20 percent bottom line growth through 2007." (emphasis added). ¶¶ 176-77. With respect to the safety of Tsyabri, Defendants falsely stated that the drug had a "good . . . safety profile" with virtually no serious side effects. ¶ 306. In addition, Defendants aggressively represented that Tysabri was a "blockbuster" drug that would: "capture the lion's share of the [$4 billion] MS market" (¶ 235),

"move quickly in the first line therapy" for treating MS (¶ 280) and "***revolutionize the treatment of MS and become the leading choice for patients and physicians***." ¶ 272 (emphasis added).

However, Defendants' statements concerning the purported safety and marketability of Tysabri were materially false and misleading because, as Plaintiffs allege in laboring detail, Defendants failed to disclose that: (i) Tysabri was a highly dangerous drug that severely suppressed the immune system and had already caused the ***deaths*** of patients taking the drug during its clinical trials; (ii) other patients taking the drug had developed ***life-threatening opportunistic infections,*** which are otherwise extremely rare and only occur in patients with severely compromised immune systems; and (iii) due to Tysabri's substantial risks, the drug was never an appropriate treatment for the expansive market the Defendants had represented. ¶¶ 15, 63-67, 133-34. Thus, the potential market for Tysabri was merely a fraction of the purported $4 billion market that Defendants represented to investors. *Id.*

C. Defendants Deliberately Failed To Disclose Known Opportunistic Infections That Occurred During The Tysabri Clinical Trials To The FDA, In Violation Of FDA Regulations

FDA regulations require physicians participating in the clinical trials to keep written documentation of all adverse events that occur in patients participating in the clinical trials and promptly report them to the sponsor (Biogen and Elan). ¶ 123. The sponsor must report any adverse event to the FDA "*that is both serious and unexpected . . . as soon as possible . . .* " ¶ 125. As discussed above, Defendants knew during the Class Period that numerous serious opportunistic infections had occurred during the Tysabri clinical trials.[5] Moreover, Defendants have admitted that they were aware that patients had ***died*** from certain of these opportunistic infections. ¶ 133. However, Defendants failed to disclose these infections and deaths to

[5] Among these infections were Pulmonary Aspergillosis, Pneumocystis Carinii Pneumonia, PML, Herpes Virus Infections, Cryptosporidial Gastroenteritis, Mycobacterium Avium Intracellular Pneumonia and Burkholderia Cepacia Pneumonia. ¶ 134.

investors or the FDA -- knowing that these events would be the death knell of Tysabri's success and any chance of capturing the multibillion dollar market for ailing patients suffering from debilitating disease. ¶ 129.

Indeed, documents submitted to the FDA confirm that Defendants concealed numerous known opportunistic infections from the FDA, prior to applying for, and receiving, fast-track approval of Tysabri. Specifically, according to a November 23, 2004 memorandum to Karen Weiss, M.D., Director at the FDA, from David Ross, M.D., Ph.D., Deputy Director on the FDA committee that approved Tysabri (the "Ross Memo"), the data the Company submitted to the FDA did not include any evidence of opportunistic infections resulting from the drug. ¶ 130. In this regard, Dr. Ross stated that: "[t]he events reported ***do not appear to represent infections due to opportunistic pathogens***." *Id.* Moreover, the FDA documents that outline the scope of Tysabri approval, made no mention of any opportunistic infections, or any associated risks. ¶ 129-31. These documents clearly demonstrate that the FDA was not informed with respect to the opportunistic infections and deaths that occurred in the Tysabri clinical trials.

D. Defendants Withdraw Tysabri From The Market

On February 28, 2005, after it was reported that an additional patient taking Tysabri had died from an opportunistic infection, PML, which is also directly linked to severe immunosuppression, Defendants withdrew Tysabri from the market. Compl., n.3. Defendants further revealed that another patient participating in the clinical trials had also contracted PML as a result of the drug's severe immunosuppressive effects. Defendants subsequently admitted that these two patients ***had actually begun exhibiting signs and symptoms of PML as early as October 2004***. ¶¶ 322, 324. On March 1, 2005, Defendants further revealed that a third patient in the Crohn's clinical trials, who was misdiagnosed with brain cancer in 2003, had actually died

from PML. ¶¶ 324, 328. As alleged in the Complaint, the PML cases were completely consistent with earlier serious opportunistic infections that occurred in the Tysabri clinical trials, of which Defendants were aware prior to and during the Class Period. ¶¶ 132-150.

E. The FDA Re-Approves Tysabri With Highly Restricted Distribution

On June 5, 2006, the FDA announced it had approved the return of Tysabri to the market for treating MS, but recommended that Tysabri be used ***only*** as a last resort therapy for MS patients in whom no other therapy was tolerable or effective. ¶ 359. Not surprisingly, the FDA required Defendants to include a "***black-box***" warning, its strictest warning, on the Tysabri label, concerning PML. ¶ 362. The FDA also required that the Tysabri label include warnings of the numerous opportunistic infections, described above. ¶ 362-64. Significantly, each of these opportunistic infections, of which Defendants were aware, was ultimately included in the new Tysabri label approved by the FDA in connection with its re-approval of Tysabri. ¶ 363. The FDA further required Defendants to implement the TOUCH Prescribing Program, a stringent risk management plan requiring patients to meet certain strict conditions in order to participate in the program and to travel to registered infusion centers to get the drug. ¶¶ 360-61. These facts indeed support Plaintiffs' claims that the widespread market distribution which Defendants had promised investors was never a possibility.

ARGUMENT

I. THE REQUIREMENTS FOR PLEADING FRAUD UNDER RULE 9(b) AND THE PSLRA IN THE CONTEXT OF A MOTION TO DISMISS

A. Defendants Cannot Meet Their Heavy Burden Under Rule 12(b)(6)

In reviewing a motion to dismiss, even in a PSLRA case, the court must "draw all reasonable inferences from the particular allegations in the plaintiff's favor . . . ." *Aldridge v. A.T. Cross Corp.*, 284 F.3d 72, 78 (1st Cir. 2002). A motion to dismiss "is one of limited

inquiry, focusing not on 'whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims.'" *Schaffer v. Timberland Co.*, 924 F. Supp. 1298, 1305 (D.N.H. 1996). The Court may dismiss the complaint only if "it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Roeder v. Alpha Indus., Inc.*, 814 F.2d 22, 25 (1st Cir. 1987) (citations omitted). Courts must also consider the allegations in the complaint in the aggregate. *In re Cabletron Systems, Inc.*, 311 F.3d 11, 32 (1st Cir. 2002). For the reasons stated below, Defendants have not met their burden under Rule 12(b)(6).

B. Plaintiffs Have Pled Highly Particularized Facts Demonstrating Defendants' Fraud

1. Rule 9(b) And The PSLRA's Pleading Standard

Federal Rule of Civil Procedure 9(b) provides that "[i]n all averments of fraud . . . the circumstances constituting fraud . . . shall be stated with particularity." Fed. R. Civ. P. 9(b). The PSLRA requires Plaintiffs to "specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading." 15 U.S.C. §78u-4(b)(1)(B). With regard to scienter, although the PSLRA requires that Plaintiffs "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind," (15 U.S.C. § 78u-4(b)(2)), the inference of scienter "need not be irrefutable." *Cabletron*, 311 F.3d at 38. Indeed, on a motion to dismiss, "the normally rigorous particularity rule has been relaxed somewhat where the factual information is peculiarly within the defendant's knowledge or control." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1418 (3d Cir. 1997).

2. Plaintiffs Are Not Required To Plead Evidence

Defendants erroneously contend that Plaintiffs are required to plead conclusive proof of Defendants' fraud to satisfy their pleading burden under the PSLRA and Rule 9(b). *See* Defs.'

Mem. 12, 15-16. However, that kind of evidence pleading is not required at this phase of the litigation and is only reserved for summary judgment or trial. *Shaw v. Digital Equip. Corp.*, 82 F.3d 1194, 1225 (1st Cir. 1996) (In determining the adequacy of a complaint under Rule 9(b), "***we cannot hold plaintiffs to a standard that would effectively require them, pre-discovery, to plead evidence***." *Id*. at 1194, 1225 (citation omitted) (emphasis added). Thus, "courts will allow private securities fraud complaints to advance past the pleading stage when some questions remain unanswered" if "the complaint as a whole is sufficiently particular . . . ." *Cabletron*, 311 F.3d at 32 (citations omitted); *see also In re Atlas Air Worldwide Holdings, Inc. Sec. Litig.*, 324 F. Supp. 2d 474, 488 (S.D.N.Y. 2004) ("Plaintiff need not plead dates, times and places with absolute precision.") (citation omitted).

As discussed fully below, the specific facts alleged in the Complaint adequately support Plaintiffs' claim of fraud. Accordingly, taking Plaintiffs' specific and well-pled allegations of fact as true, as they must be taken, Defendants' motion should be denied.

II. THE COMPLAINT AMPLY PLEADS FRAUD WITH PARTICULARITY

Defendants do not contest that the Complaint adequately specifies the allegedly false and misleading statements and omissions -- *i.e.* the who, what, when and where of Defendants' fraud -- and the reasons why those statements were misleading when made. Defs.' Mem. 12. Indeed, Plaintiffs clearly meet that requirement. *See, e.g.*, ¶¶ 164-323. Rather, Defendants' only arguments are that: (i) the Complaint does not allege particularized facts demonstrating that Defendants knew that Tysabri ***caused*** the opportunistic infection, PML; and (ii) the Complaint fails to specify ***when*** Defendants knew that Tysabri caused PML. Defs.' Mem. 17, 20.[6]

[6] In this regard, Defendants attempt to require Plaintiffs to plead details, which are unnecessary at this phase of the litigation. *See Cabletron*, 311 F.3d at 32 (citations omitted); *see also Atlas Air*, 324 F. Supp. 2d at 488.

Defendants' contentions regarding the allegations contained in the Complaint are completely unfounded. The Complaint clearly provides particularized facts demonstrating that, prior to and during the Class Period, Defendants knew (or recklessly disregarded) that Tysabri caused PML as well as ***additional*** opportunistic infections in patients taking Tysabri during the Class Period, and that certain patients had actually ***died*** from these infections during the drug's clinical trials. These particularized allegations are fully discussed below.

A. The Complaint Alleges Particularized Facts Demonstrating That Defendants Knew Tysabri Caused Life-Threatening Infections And Deaths, And When Defendants Knew Such Facts

Plaintiffs have alleged specific facts, including ***Defendants' own admissions***, demonstrating that Defendants knew Tysabri ***caused*** severe, if not fatal, opportunistic infections in patients taking the drug during its MS and Crohn's clinical trials, prior to and during the Class Period. ¶¶ 132-51.[7] In particular, Plaintiffs have alleged that Defendants were aware that at least 11 different types of opportunistic infections indicative of severe immunosuppression occurred in patients taking Tysabri ***during*** the drug's clinical trials. ¶ 134. Those infections include Pulmonary Aspergillosis, Pneumocystis Carinii Pneumonia, PML, Herpes Virus Infections, Cryptosporidial Gastroenteritis, Mycobacterium Avium Intracellular Pneumonia and Burkholderia Cepacia Pneumonia, all of which are directly associated with immunosuppression. *Id.* Plaintiffs have further alleged that Defendants were aware that at least 19 different types of opportunistic infections occurred in at least 60 patients taking Tysabri after FDA approval. ¶

[7] Plaintiffs have also addressed the particularity arguments contained in Defendants' Memorandum and Exhibit A in the chart attached hereto as Plaintiffs' Exhibit.

153.[8] Again, these events were material adverse developments impacting Tysabri's safety and marketability which required disclosure.

With respect to the 11 types of infections that occurred ***during*** the Tysabri clinical trials, the Complaint further alleges Defendants were aware that several infections, including Pulmonary Aspergillosis and Pnemocystis Pneumonia, ***caused*** the ***deaths*** of patients taking Tysabri. ¶ 133. In this regard, Plaintiffs allege that Defendants were aware of such data by at least the following dates, when the trial results were reported: (i) Phase I of the MS trials by 1995 (¶ 87); (ii) Phase II of the MS trials by September 2001 (¶ 88); (iii) Phase II of Crohn's trials by May 23, 2001 (¶ 91); (iv) Phase III of the Crohn's ENACT-1 study by July 24, 2003 (¶ 91); (v) Phase III of the ENACT-2 study by January 29, 2004 (¶ 92); and (vi) the first year of Phase III of the MS trials by February 18, 2004. ¶ 90. Accordingly, Defendants were aware of the numerous opportunistic infections and related deaths that occurred during the clinical trials by February 2004, prior to the Class Period.[9]

---

[8] Defendants confuse Plaintiffs' allegations concerning the opportunistic infections that occurred in Tysabri patients by improperly comparing allegations of opportunistic infections that occurred ***during*** the Tysabri clinical trials with those that occurred ***after*** Tysabri was approved for commercial use. Defs.' Mem. 16, 21. However, Plaintiffs clearly allege that at least 11 types of opportunistic infections occurred ***during*** the clinical trials (¶ 134), prior to FDA approval, while the 60 infections occurred ***after*** the trials. In any event, the precise number of infections and whether they are opportunistic, (Defs.' Mem. 17 n. 11), are issues of fact, not properly decided on a motion to dismiss. *See Cabletron*, 311 F.3d at 34.

[9] The cases Defendants cite in this regard are easily distinguishable. In those cases, unlike here, the court found that plaintiffs' allegations consisted of vague assertions with few particular facts. *See Carney v. Cambridge Tech. Partners, Inc.*, 135 F. Supp. 2d 235 (D. Mass. 2001) (granting motion to dismiss where plaintiffs failed to plead the source of the facts and reasons for their belief that defendants committed the fraud); *Maldonado v. Dominguez*, 137 F.3d 1 (1st Cir. 1998) (finding no strong inference of scienter because the individual defendants were not senior officers of the company and the complaint lacked specific facts implying fraudulent intent). Here, Plaintiffs have alleged numerous specific facts demonstrating Defendants' knowledge, or reckless disregard for the true risks of Tysabri.

Moreover, Plaintiffs allege that three confidential sources, CS 3, CS 4 and CS 5, neurologists intimately involved in the MS and Crohn's clinical trials, confirmed that during the clinical trials, patients taking Tysabri had developed opportunistic infections, including Cryptosporidiosis infection, Pneumocystis Carinii Pneumonia and Atypical Mycobacterial infections. ¶¶ 117, 134, 144-45. CS 4 further confirmed that Defendants were aware prior to and during the Class Period that Tysabri caused such infections. ¶ 117.

As Plaintiffs further allege, at the March 2006 FDA Hearing, Defendants further confirmed that, prior to and during the Class Period, they were aware of the serious opportunistic infections described above, which occurred during the Tysabri clinical trials. ¶¶ 132-39. Specifically, the Complaint alleges that, at the March 2006 FDA Hearing, Dr. Michael Panzara, Director of Medical Research ***at Biogen***, described numerous serious opportunistic infections including, among others, PML, Herpes Virus infection, Pneumocystis Carinii Pneumonia and Pulmonary Aspergillosis, that the Company observed during the Tysabri clinical trials. ¶ 134. According to Dr. Panzara, these infections, which ***only occur*** in persons with severely compromised immune systems, were indicative of "a comprise in cell-mediated immunity." *Id.* Dr. Panzara further noted that Herpes infections "occurred with greater frequency in Tysabri treated patients," which he directly attributed to severe immunosuppression. *Id.*[10] These facts unequivocally demonstrate that Defendants were aware during the Class Period of numerous life-

[10] In a further attempt to escape liability, Defendants contend that Plaintiffs have not "alleged the particulars" of how Biogen knew of "any adverse event reported during the Crohn's trials." Defs.' Mem. 24. However, the Complaint alleges numerous particularized facts showing Defendants knew, or recklessly disregarded opportunistic infections that occurred in the Crohn's trials, including, but not limited to: (i) Defendants were aware of the clinical trial results by February 2004 (¶¶ 94-99); (ii) Defendants admit that physicians working as investigators in the clinical trials reported all adverse events to Biogen (Defs.' Mem. 7); (iii) Defendant Mullen admitted that he spoke regularly with Elan's CEO, concerning issues related to Tysabri (¶¶ 76, 141); and (iv) CS 3, CS 4 and CS 5, neurologists intimately involved in the MS and Crohn's trials, corroborated Defendants' knowledge in this regard (¶¶ 117, 134, 144-45).

threatening infections directly linked to Tysabri and contradict Defendants' public statements that Tysabri had a "good tolerability and safety profile."

Accordingly, Plaintiffs have provided sufficiently particularized facts demonstrating Defendants knew that Tysabri caused life-threatening opportunistic infections.[11]

B. The Complaint Alleges Particularized Facts Demonstrating That Defendants Knew Of, Or Recklessly Disregarded, Adverse Warnings Of Tysabri's Severe Immunosuppressive Effects Prior To And During The Class Period

The Complaint also provides sufficiently particularized facts demonstrating that Defendants knew of, or recklessly disregarded, countless additional red flag warnings confirming that Tysabri's highly immunosuppressive characteristics undermined its safety and marketability. These warnings included findings describing the severe immunosuppressive effects of the drug and were: (i) reported in scientific and medical journals; (ii) presented by the co-inventor of Tysabri at industry conferences that senior Biogen officials attended; and (iii) reflected in animal studies conducted by Defendants.[12]

Specifically, in an April 2001 article co-authored by Dr. Stephen D. Miller and Biogen's Dr. Cheryl Nickerson-Nutter, in *The Journal of Clinical Investigations*, which Plaintiffs

---

[11] Defendants erroneously rely on *Orton v. Parametric Tech. Corp.*, 344 F. Supp. 2d 290, 299 (D. Mass. 2004), to support their argument that Plaintiffs' allegations lack the requisite particularity. Defs.' Mem. 15. In *Orton*, unlike here, the plaintiffs' allegations omitted basic facts, such the identity of the person making the false and misleading statements at issue, and when such statements were allegedly made. Here, as shown above, the Complaint alleges highly particularized facts concerning Defendants' misstatements as well as their scienter.

[12] Given that Defendants viewed Tysabri as Biogen's primary source of future growth, Defendants, as senior executives of the Company, knew, or were reckless in not keeping themselves informed, of the material developments concerning Tysabri. *See City of Sterling Heights Police and Fire Ret. Sys. v. Abbey Nat'l, PLC*, 423 F. Supp. 2d 348, 362 (S.D.N.Y. 2006) (inference of recklessness may be imputed from the fact that the issue concerned a core business operation); *Atlas*, 324 F. Supp. 2d at 489-91; *Adams v. Kinder-Morgan, Inc.*, 340 F.3d 1083 (10th Cir. 2003).

reference in the Complaint, prestigious medical experts concluded that Tysabri "***has multiple effects on the immune system and may be problematic in treating established autoimmune diseases such as MS***" and thus, "[c]ontinued examination . . . will be required . . . ." ¶ 109 (emphasis added). The Complaint further alleges that, because of the results of this study, Dr. Miller recommended to senior Biogen officials when the study was completed in April 2001 that they should conduct additional animal studies. *Id.* Similarly, a May 23, 2003 article published in the *Medical Review* warned that "Tysabri block[s] the function of the immune system and interfere[s] with normal inflammatory responses to infection." ¶ 115.

In addition, the Complaint cites a July 9, 2004 article published by Dr. Steinman, the co-inventor of Tysabri, in the journal, *Science*, in which he expresses his concerns about the "serious risks" that Tysabri posed to patients on the drug because "recipients of the therapy would become generally compromised in their ability to fight infection." ¶ 106. The Complaint further alleges that immediately after Dr. Steinman published his study in July 2004, ***Biogen executives*** specifically asked Dr. Steinman to "***tone down criticisms of the drug***," which he had reiterated during several of his speeches. ¶ 334. Dr. Steinman further warned about the exact same risks he discussed in his article, at industry conferences held in September 2004 in Venice, Italy and in January 2005 in Montana, in which ***senior Biogen officials attended***. ¶ 118.

The Complaint further alleges the specific dates of additional animal studies subsequently conducted by Biogen and Elan, which all noted "unexplained deaths." ¶¶ 103-05, 108, 114, 116-17. Moreover, at least one animal study (Biogen Study # 309-010-01) reported an unidentified mass, which scientists conducting that study concluded may be the result of severe immunosuppression. ¶ 103. In spite of Dr. Steinman's earlier warnings and the results described above, Defendants did not follow up on the results of any of the animals studies, which

warned that Tysabri was a severely immunosuppressive drug. At a minimum, Defendants were reckless in not following up and fully evaluating the results of these animal studies.[13] In any event, Defendants began administering Tysabri to humans in clinical trials.

C. Plaintiffs' Confidential Sources Are Pled With Ample Particularity

Plaintiffs cite eight confidential sources whose accounts further corroborate Plaintiffs' allegations of Defendants' fraud. In *Cabletron*, the First Circuit endorsed the Second Circuit's test for pleading confidential source materials as follows:

> Look at all the facts alleged to see if they 'provide an adequate basis for believing that the defendants' statements were false,' which involves an evaluation of "the level of detail provided, . . . the corroborative nature of the other facts alleged (including from other sources), the coherence and plausibility of the allegations, the number of sources, the reliability of the sources, and similar indicia.

311 F.3d at 11 (citations omitted).

Defendants' blanket charge that none of Plaintiffs' confidential sources are pled with particularity, without Defendants identifying any specific source or specific details concerning the Complaint's purported deficiencies, must be rejected. Defs.' Mem. 22-24. As discussed below, Plaintiffs have clearly met their burden for pleading confidential sources in this Circuit.[14]

With respect to each source, Plaintiffs have pled the source's position, the dates the source was employed in that position and the duties of that position, demonstrating the witnesses were clearly in a position to know the facts stated in their accounts. *See, e.g.*, ¶¶ 69, 71, 99, 117,

---

[13] Knowledge or reckless disregard for negative data arising from animal studies can support a strong inference of scienter. *In re Sepracor, Inc. Sec. Litig.*, 308 F. Supp. 2d 20 (D. Mass. 2004).

[14] Defendants' reliance on *In re Vertex Pharm., Inc. Sec. Litig.*, 357 F. Supp. 2d 343 (D. Mass. 2005), is misplaced. In *Vertex*, the court found the plaintiff's allegations insufficient because the confidential witnesses did not have personal knowledge of the facts they state. *Id.* at 353-54. Nor were their statements corroborated by independent facts. *Id.* Here, Plaintiffs' confidential sources are alleged to have personal knowledge of the facts they state, which are also corroborated by other witnesses' accounts and/or other independent evidence.

144-50, 156-57. Moreover the Complaint alleges that each confidential source had personal knowledge of the facts stated in their accounts, which, as the Complaint states are corroborated by independent evidence and/or other witnesses' accounts, further supporting the reliability of these witnesses' statements.[15] Nothing more is required.

III. PLAINTIFFS HAVE ADEQUATELY ALLEGED THEIR CLAIMS UNDER SECTION 10(b) OF THE EXCHANGE ACT AND SEC RULE 10b-5

To state a claim under Section 10(b) of the Securities Exchange Act of 1934 ("Exchange Act") and Rule 10b-5 promulgated thereunder (17 C.F.R. § 240.110b-5), "plaintiffs must allege 'with particularity' that defendants: (1) made a misstatement or omission of material fact; (2) with scienter; (3) in connection with the purchase or sale of a security; (4) upon which plaintiffs reasonably relied; and (5) plaintiffs' reliance was the proximate cause of their injury." *In re Stone & Webster, Inc. Sec. Litig.*, 414 F.3d 187, 192-93 (1st Cir. 2005). As demonstrated below, the Complaint fully satisfies the applicable pleading standard.

A. Materiality And Defendants' Duty To Disclose

Under the federal securities laws, in order for there to be a duty to disclose certain facts to investors in connection with their purchase or sale of securities, the facts must be material. *Basic, Inc. v. Levinson*, 485 U.S. 224, 231-32 (1988). A fact is material if it is substantially likely "that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." *Id.* When a corporation makes a disclosure, there is a duty to make it ***complete and accurate*** so as not to mislead. *Cabletron*, 311 F.3d at 36; *Brumbaugh v. Wave Sys. Corp.*, 416 F. Supp. 2d 239, 250

[15] The credibility of confidential sources is an issue reserved for trial. *Fitzer v. Security Dynamics Techs.*, 119 F. Supp. 2d 12, 21 (D. Mass. 2000).

(D. Mass. 2006) ("by volunteering 'relevant, material information' . . . [d]efendants assumed an obligation . . . to convey 'the whole truth.'").

Plaintiffs clearly allege that, throughout the Class Period, Defendants made numerous public statements concerning the safety (*See, e.g.*, ¶¶ 180-81, 203-04) and marketability (*See, e.g.*, ¶¶ 234-35, 251) of Tysabri. These topics were of the utmost materiality to investors and the market. Indeed, analysts following Biogen highlighted the significance of Tysabri's safety and marketability, stating, for example, that they were "***encouraged to see such a clean safety profile for***" the drug and "***expect rapid adoption of the drug and peak sales of at least $3 billion per year***." ¶¶ 212, 218. By choosing to comment on such topics, Defendants were obligated to speak truthfully and avoid misleading the market. In this regard, Defendants should have disclosed all material facts relating to Tysabri, including negative facts concerning the serious risks associated with the drug, as well as the severe opportunistic infections and deaths that occurred in the clinical trials.[16] Indeed, courts have found, in particular, that adverse information regarding clinical trials, which could limit the marketability of a drug, is highly material and must be disclosed to investors.[17]

---

[16] Defendants confuse their disclosure obligations under the federal securities laws with their obligations to the FDA, spending nearly eight pages addressing whether Plaintiffs adequately pled that Defendants failed to disclose opportunistic infections to the FDA. The issue before the Court, however, is ***Defendants' duty to disclose to the investing public***. Defs.' Mem. 18-24.

[17] *See, e.g., In re Transkaryotic Therapies, Inc. Sec. Litig.*, 319 F. Supp. 2d 152 (D. Mass. 2004) (failure to disclose adverse clinical trial data and negative FDA review letter were material omissions directly affecting the drug's marketability); *Sepracor*, 308 F. Supp. 2d at 20 (denying defendants' motion to dismiss, in part, finding information regarding a drug's adverse side effects was material, given the potential risk to the drug's marketability); *In re PLC Systems, Inc. Sec. Litig.*, 41 F. Supp. 2d 106 (D. Mass. 1999) (motion to dismiss denied where defendants misrepresented material facts about clinical trials); *In re Neopharm, Inc. Sec. Litigation*, No. 02C2976, 2003 U.S. Dist. LEXIS 1862, at *43-44 (N.D. Ill. Feb. 7, 2003) (finding defendants' statements actionable where defendants omitted disclosure of material problems associated with the drug).

B. The Complaint Alleges Facts Giving Rise To A Strong Inference That Defendants Acted With Scienter

1. Plaintiffs Have Alleged Facts Giving Rise To Strong Circumstantial Evidence Of Conscious Misbehavior Or Extreme Recklessness

Plaintiffs have also clearly alleged facts in the Complaint, which give rise to a "strong inference" that Defendants knew, or at a minimum, recklessly disregarded, that Biogen's public statements were false and misleading when made. *See Cabletron*, 311 F.3d at 38 (recklessness is sufficient to plead scienter under Section 10(b) and Rule 10b-5). In making the scienter determination, a court must evaluate "the totality of the circumstances." *Crowell v. Ionics Inc.*, 343 F. Supp. 2d 1, 13 (D. Mass. 2004).

Defendants' knowledge, or reckless disregard for numerous facts alleged in the Complaint, creates a strong inference of scienter. Specifically, as set forth in Section II above, Plaintiffs have specifically alleged that Defendants: (1) knew that Tysabri debilitates, if not entirely compromises, one's immune system (¶¶ 98-99); (2) have admitted that serious opportunistic infections occurred during the Tysabri clinical trials (¶¶ 132-40); (3) were aware of the majority of the Tysabri clinical trials revealing the opportunistic infections that occurred (¶ 95); (4) concealed opportunistic infections from the FDA prior to the FDA's approval of Tysabri, in violation of FDA regulations (¶¶ 129-51); (5) had access to medical and scientific journals containing specific warnings of the risks of Tysabri (¶¶ 113-17); (6) participated in industry conferences where the severe immunosuppressive effects of Tysabri were discussed (¶ 118); (7) had a duty to disclose the infections to each other under the Collaboration Agreement (¶¶ 76-79);[18] and (8) had access to animal study test results warning that Tysabri was highly immunosuppressive (¶¶ 101-12).

[18] Allegations of this type of collaboration agreement support scienter. *Neopharm*, at *35-6.

Accordingly, Plaintiffs have sufficiently alleged facts establishing Defendants' knowledge or recklessness concerning the alleged fraud and demonstrating that, despite Defendants' contentions, this case is not based upon "fraud by hindsight."

2. Defendants' Deliberate Scheme To Conceal Serious Opportunistic Infections From The FDA Further Supports Scienter

As discussed above, the Complaint alleges that Defendants failed to disclose serious opportunistic infections to the FDA, in violation of FDA regulations, which required them to disclose such infections. Defendants cannot simply rest on the FDA's approval of Tysabri as a license to commit securities fraud. Moreover, courts routinely find that a defendant's deliberate engagement in illegal behavior demonstrates scienter. *Novak v. Kasaks,* 216 F.3d 300, 311 (2d Cir. 2000); *In re Novastar Fin. Sec. Litig.*, No. 04-0330-CV-W-ODS, 2005 U.S. Dist. LEXIS 19946, at *22 (W.D. Mo. May 12, 2005). As described below, Defendants' violation of FDA regulations further demonstrates their scienter.

The Complaint alleges particularized facts demonstrating Defendants' failure to disclose serious opportunistic infections to the FDA, in violation of FDA regulations. In this regard, the Complaint cites the Ross Memo, which clearly demonstrates that Dr. Ross, the Deputy Director of the FDA committee that approved Tysabri, was not provided with ***any evidence of opportunistic infections***. ¶ 130. Moreover, as Defendants admit in their Memorandum, none of the FDA materials, including the medical review approving Tysabri for commercial use or the Tysabri label, included any mention of opportunistic infections. Defs.' Mem. 19, 22, n. 9. Defendants further admit that they did not disclose any opportunistic infections to the FDA until

March 2006. ¶ 132-40.[19] At this pleading stage of the litigation, the Court must draw all inferences in favor of Plaintiffs. *See Aldridge*, 284 F.3d at 78.

3. Plaintiffs' Confidential Source Allegations Corroborate The Complaint's Other Allegations Concerning The Defendants' Scienter

As discussed in Section II above, the Complaint has also sufficiently alleged particularized facts demonstrating the reliability of the confidential witnesses' accounts, which corroborate Defendants' scienter. Courts routinely find that confidential source accounts that corroborate the Complaint's allegations support a strong inference of scienter. *See Sekuk Global Enters. v. KVH Indus.*, No. 04-306ML, 2005 U.S. Dist. LEXIS 16628 (D.R.I. Aug. 11, 2005). Here, numerous confidential sources have conformed Defendants' knowledge that Tysabri was a highly dangerous drug that caused numerous opportunistic infections in patients taking the drug during the Tysabri clinical trials.

As mentioned briefly above, CS 4 further confirmed that Defendants were aware prior to and during the Class Period that Tysabri caused such infections. ¶ 117. Moreover, CS 6, a former Data Entry Clerk for Randstad from May to December 2004 employed by Biogen to track adverse events that occurred in the Tysabri MS clinical trials, recalled that a large volume of adverse events were reported during the Tysabri trials. ¶ 148. According to CS 6, the volume of adverse events that this witness observed was far greater than those observed in other clinical trials in which this witness was involved. *Id.* Moreover, CS 6 recalled that the number of adverse events reported was particularly high in June 2004 and in November 2004, just before

[19] Defendants erroneously contend that the Ross Memo recommending approval of Tysabri considered only safety data provided by the Company through April 30, 2004. Defs.' Mem. 22. In fact, the Ross Memo states the Dr. Ross considered ***all data*** provided by the Company in the Tysabri application, not simply data through April 30, 2004. *See* Defs.' Mem. App. Ex. at 9, 14. Accordingly, Defendants failed to provide information concerning such infections to the FDA prior to its approval of Tysabri. ¶ 129.

the FDA approved Tysabri and that approximately ***sixty to seventy adverse events were reported daily*** during the MS trials. *Id.* The sheer volume of adverse events and Defendants absolute failure to report any material level of adverse events is highly probative of Defendants' scienter.

In addition, CS 2, CS 3, CS 4 and CS 5, who were all neurologists that worked directly with patients taking Tysabri in the MS and Crohn's further confirmed that patients developed the following opportunistic infections: Pneumocystis Carinii Pneumonia, Cryptosporidiosis, Atypical Mycobacterial infection and certain cancers, all indicative of severe immunosuppression. ¶¶ 117, 144-45, 147.

Finally, according to CS 7, a Professor of Neurology with expertise in immunology of the central nervous system and MS, and CS 8, a senior scientist at the National Institute of Health specializing in the JC virus and PML, the purported misdiagnosis of the Crohn's patient in July 2003 as having brain cancer was highly suspicious. ¶¶ 156-57. CS 7 and CS 8 stated that they believe that the purported misdiagnosis of PML as brain cancer was the result of either an effort by Defendants to conceal the true diagnosis or malpractice on the part of the neuropathologist because the two are completely dissimilar. *Id.*[20]

4. Plaintiffs Further Establish Defendants' Scienter Through Motive And Opportunity

A defendant's scienter may also be established by alleging "concrete benefits that could be realized by . . . the false statements and wrongful nondisclosures" and that the defendant had "the means and likely prospect of achieving concrete benefits by the means alleged" to commit the fraud. *Aldridge*, 284 F.3d at 82 (citation omitted).[21] Here, Plaintiffs have alleged

[20] In any event, this matter constitutes an issue of fact which is inappropriate at this phase of the litigation. *See Cabletron*, 311 F.3d at 34.

[21] Defendants do not, and cannot, dispute that they had the opportunity to commit fraud as high-ranking Officers of the Company responsible for its day-to-day operations. ¶¶ 33-38.

Defendants' motive and opportunity through substantial insider trading and executive compensation.

a. Defendants' Unusual Insider Trading, Alone, Creates A Strong Inference of Scienter

In the First Circuit, allegations of insider trading create a strong inference of scienter if they are in suspicious amounts and at suspicious times. *See Shaw*, 82 F.3d at 1224; *In re SmarTalk Teleservices, Inc. Sec. Litig.*, 124 F. Supp. 2d 527 (S.D. Ohio 2000). Defendants do not challenge Plaintiffs' allegations that the Individual Defendants sold a suspicious amount of their personal holdings of Biogen stock for proceeds of ***$137,233,850***. ¶ 387.

As an initial matter, Defendants' Memorandum woefully fails to acknowledge or defend the severe insider misconduct of Defendant Bucknum, who, upon learning on February 18, 2005 at a Biogen Board of Directors meeting of an additional PML-related fatality in the Tysabri test group (and knew the obvious materiality of the information and predictable market impact),[22] proceeded to sell ***89,700 shares*** of Biogen common stock -- ten days before the end of the Class Period -- for net proceeds of ***$1.9 million***. As a result of these acts, the SEC immediately commenced a formal investigation, which remains pending against the Company on a broadened scale concerning Tysabri's withdrawal, and filed an enforcement action against Defendant Bucknum, who quickly settled with the SEC, ***paying $3 million in disgorgement interest and***

[22] Bucknum's insider selling supports the Complaint's allegations of the highly material nature of the PML incidents in the clinical trials as well as the other deadly and severely debilitating opportunistic infections. Indeed, if, as Defendants contend, the purportedly anomalous infections did not undermine the safety and efficacy of the drug (Defs.' Mem. 16), why would the Company's General Counsel risk his livelihood trading Biogen shares after learning of a PML-related fatality? Moreover, why, based on the facts plead in the Complaint, would the federal agency monitoring controlled medication, completely curtail further use of Tysabri and impose the most rigorous protocol in history for a drug which Defendants had proclaimed would capture an entire market in "blockbuster" fashion -- a promise which will never be fulfilled to patients suffering from debilitating ailments?

penalties. The SEC also ***prohibited Defendant Bucknum from serving as an officer or director of a public company for five years***. These facts obviously demonstrate insider misconduct at the most senior executive level and provide compelling evidence of Bucknum's scienter.

With regard to the remaining insider sales, Defendants' argue that such sales do not create an inference of scienter because they were made pursuant to a 10b5-1 stock trading plan. Defs.' Mem. 27.[23] However, Defendants' argument regarding the purported 10b5-1 Plan mischaracterizes the facts in the Complaint entirely and are otherwise of no weight.[24] First, since Defendants' 10b5-1 plans are neither publicly available, nor referenced in the Complaint, their existence is not "capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned," and, thus, cannot be considered by the Court at this juncture. *See* Fed. R. Evid. 201(b)(2). Second, Defendants do not provide a copy of the plans, nor do they state when they entered into the plan or other relevant details.[25] The Court cannot accept these unsupported and self-serving assertions, especially where such facts are not alleged in the Complaint. Any evaluation of Defendants' purported trading plans would require a fully developed factual record, and, thus, is not proper for a motion to dismiss. *See In re Cardinal*

---

[23] Defendants erroneously argue that, since Defendant Kellogg did not sell any Biogen securities during the Class Period, there is no "scintilla of any inference of scienter as to him." Defs.' Mem. 26 n. 13. Defendant Kellogg's lack of insider selling in no way mitigates his knowledge or reckless disregard of Tysabri's risks and thus, cannot absolve him from liability for the false and misleading statements he made while in possession of such information. *See Crowell*, 343 F. Supp. 2d at 14-15 ("The absence of insider trading does not preclude an inference of scienter") (citing *Cabletron*, 311 F.3d at 40).

[24] Defendants attach Exhibit B to further illustrate their argument. Plaintiffs have addressed this argument fully in their opposition Memorandum.

[25] In any event, 10b5-1 plans may actually afford insiders an opportunity to "manipulate the timing and content of disclosures related to material information . . . ." *See* Alan D. Jagolinzer, *An Analysis of Insiders' Information-based Trade Within the SEC Rule 10b5-1 Safe Harbor*, STANFORD U. GRADUATE SCHOOL OF BUSINESS, 5-7 (2005).

Health, Inc. Sec. Litig., 426 F. Supp. 2d 688, 734 n.58 (S.D. Ohio 2006) (A 10b5-1 trading plan is "typically considered an affirmative defense" and is therefore premature to be considered in a motion to dismiss); *see also Illinois State Bd. of Investment v. Amerigroup, Corp.*, No. 2:05-CV-701 (E.D. Va. July 20, 2006).[26]

With respect to the Individual Defendants, the Complaint alleges that each of their sales was suspicious in amount, ranging from 50% to 100% more stock than they sold in the two years prior to the Class period. ¶¶ 387- 92. Moreover, the Complaint alleges that the Individual Defendants' sales were strategically timed to coincide with key dates -- including announcements of Defendants' intention to seek fast-track approval of Tysabri and earnings announcements -- when the price of Biogen stock was at a high and Defendants were in possession of adverse, material non-public information about Tysabri. ¶¶ 164, 178-180, 213-16, 394. Thus, Defendants' insider trading further compels a strong inference of scienter.

b. Defendants' Desire to Earn Substantial Bonuses Supports An Inference Of Scienter

Defendants were also motivated to conceal Tysabri's severe immunosuppressive effects to maximize their annual bonuses. ¶ 397-401. Evidence that Defendants stood to receive substantial bonuses, and, such bonuses are dependant upon the company's financial performance, as is the case here, supports an inference of scienter. *See No. 84 Employer-Teamster Joint*

[26] Defendants claim that Defendant Rohn's sales are not suspicious because he purportedly sold his stock in connection with his retirement. Defs.' Mem. 27. However, the fact remains that Rohn sold his shares at suspicious times (*i.e.* February 18, 2004 - the day Defendants announced their intention to seek fast-track approval of Tysabri), well before he announced his retirement in November 2004. *Id.* Thus, these sales support his scienter. *See Ruskin v. TIG Holdings, Inc.*, No. 98 Civ. 1068 LLS, 2000 U.S. Dist. LEXIS 11517, at *14-16 (S.D.N.Y. Aug. 14, 2000) (finding stock sold by insider who was "in the upper echelon of management," ***before*** he announced his retirement where such sales were inconsistent with prior trading patterns, supported a strong inference of scienter); *see also* ¶ 391, 394. Defendants' reliance on *Greebel v. FTP Software, Inc.*, 194 F.3d 185 (1st Cir. 1999) is misplaced. In *Greebel*, unlike here, one defendant sold the majority of his stock ***after*** he retired. 194 F.3d at 206.

Council Pension Trust Fund v. Am. West Holding Corp., 320 F.3d 920, 944 (9th Cir. 2003) (allegations that bonuses were tied to company's financial performance supported strong inference of scienter).[27] Moreover, it is hardly a coincidence that Biogen's Board of Directors approved these bonuses on February 17, 2005, only the day before Tysabri was withdrawn from the market. ¶¶ 400-01.

IV. DEFENDANTS' STATEMENTS ARE NOT PROTECTED BY THE STATUTORY SAFE HARBOR OR BESPEAKS CAUTION DOCTRINE

In a final attempt to obfuscate the central issues facing this Court, Defendants argue that certain of the alleged misstatements should be dismissed under the PSLRA's safe harbor, or alternatively, the bespeaks caution doctrine. Defs.' Mem. 28-29. The statutory safe harbor and bespeaks caution doctrine, however, protect only forward-looking statements if they are properly identified as such, accompanied by meaningful cautionary language and are made without actual knowledge of their falsity. 15 U.S.C. § 78u-5(c).

First, as described above, Defendants made all of the alleged false and misleading statements with actual knowledge of their falsity. *Stone & Webster*, 414 F.3d at 213 ("we do not think Congress intended to grant safe harbor protection for such a statement whose falsity consists of a lie about a present fact."). Accordingly, even if the statements they challenge were forward-looking -- which they are not -- the statements are not protected by the PSLRA.

Second, because certain statements Defendants challenge are based upon present or historical facts, they are not forward-looking and, thus, are not shielded by the PLSRA. *See, e.g.*, ¶¶ 176, 178 ("Biogen Idec ***is*** well positioned to achieve our long-term goal . . . .") (emphasis added); ¶ 181 ("there ***is*** in our minds a very large currently unserved segment of the MS

[27] *See also Barrie v. Intervoice-Brite, Inc.*, 397 F.3d 249, 264 (5th Cir. 2005); *Florida State Bd. of Admin. v. Green Tree Fin. Corp.*, 270 F.3d 645, 661 (8th Cir. 2001).

population for whom this ***will be*** a therapy that they can now consider.") (emphasis added). Moreover, mixed statements containing historical fact and forward-looking statements are not protected by the safe harbor provision.[28] *Stone & Webster*, 414 F.3d at 213 (a mixed statement of current fact and future prediction does not fall within PSLRA's safe harbor provision); *In re Cryolife, Inc. Sec. Litig.*, No. 1:02-CV-1868 (BBM), 2003 U.S. Dist. LEXIS 26170, at *48 n.6 (N.D. Ga. May 27, 2003).

Third, the statements Defendants contend are forward-looking are not protected by their purported "explicit warnings and cautionary language" because such language merely warned of ***hypothetical*** risks that ***might*** occur and, thus, did not disclose problems already existing. *See Rosenbaum Capital L.L.C. v. Boston Communs. Group, Inc.*, 445 F. Supp. 2d 170, 177 (D. Mass. 2006).[29] Indeed, none of these purported cautionary statements even mention the severe immunosuppressive effects of Tysabri or that numerous opportunistic infections occurred in patients taking Tysabri during the clinical trials. Accordingly, these hypothetical risks fail to disclose "facts critical to appreciating the magnitude of the risks described" and are, thus, not sufficiently tailored. *See In re Regeneron Pharms., Inc. Sec. Litig.*, No. 03 Civ. 3111(RWS), 2005 U.S. Dist. LEXIS 1350, at *54 (S.D.N.Y. Feb. 1, 2005) ("a warning that fails to disclose specific known facts is insufficiently precise and will not insulate Defendants' statements from liability.").[30]

---

[28] *See also* ¶¶ 184, 200-03, 214, 219, 233-34, 236, 260, 272, 280, 283-84, 295-96, 299, 301-04.

[29] *See also Sepracor*, 308 F. Supp. 2d at 34; *Asher v. Baxter Int'l Inc.*, 377 F.3d 727, 732 (7th Cir. 2004) ("boilerplate warnings won't do; cautions must be tailored to the risks that accompany the particular projections"); *In re MobileMedia Sec. Litig.*, 28 F. Supp. 2d 901, 928 (D.N.J. 1998) ("A cautionary statement must discredit the alleged misrepresentation" so that "the 'risk of real deception drops to nil.'").

[30] The cases Defendants cite in this regard are easily distinguishable. Defs.' Mem. 28-29. In those cases, unlike here, the courts found defendants' statements were accompanied by sufficient

V. DEFENDANTS ARE LIABLE FOR VIOLATING SECTION 20A

Plaintiffs have also adequately alleged a Section 20A violation against the Section 20A Defendants. To state a claim under Section 20A, plaintiffs must allege that: (1) a corporate insider traded in the company's securities; (2) while in possession of material non-public information; and (3) that the plaintiff traded contemporaneously with the corporate insider. 15 U.S.C. § 78t-1(a). Defendants do not dispute that Plaintiffs have established a prima facie case for insider trading under Section 20A against all of the Section 20A Defendants, except with regard to Defendant Bucknum. Defendants' sole argument is that Plaintiffs' Section 20A claim against Defendant Bucknum should be dismissed on the grounds that Plaintiffs have failed to plead a predicate Exchange Act violation of Section 10(b) against Bucknum. Defs.' Mem. 30 n.15. Defendants' argument, for which they cite no authority, fails because Section 20A does not require a predicate Exchange Act violation by ***each*** insider. *See* 15 U.S.C. § 78t-1(a).[31]

VI. PLAINTIFFS HAVE ALLEGED CONTROL PERSON LIABILITY

To adequately plead a control person claim under Section 20(a) of the Exchange Act, a plaintiff must allege: (1) an underlying primary violation of the securities laws; and (2) that the individual defendant has control over the primary violator. *Stone & Webster*, 414 F.3d at 194. As demonstrated above, Plaintiffs have stated actionable claims against the Individual Defendants as primary violators of Section 10(b) and Rule 10b-5. Because the Individual

---

cautionary language (*see Baron v. Smith*, 380 F.3d 49, 53-54 (1st Cir. 2004); *Meyer v. Biopure Corp.*, 221 F. Supp. 2d 195, 204 (D. Mass. 2002)) and plaintiffs did not allege that the defendants had actual knowledge. *See In re Ibis Tech. Sec. Litig.*, 422 F. Supp. 2d 294, 310-11 (D. Mass. 2005); *In re Parametric Tech. Corp. Sec. Litig.*, 300 F. Supp. 2d 206, 219 (D. Mass. 2001).

[31] *See also Quaak v. Dexia, S.A.*, 445 F. Supp. 2d 130 (D. Mass. 2006); *Johnson v. Aljian*, 394 F. Supp. 2d 1184, 1194-95 (C.D. Cal. 2004); *In re Enron Corp. Derivative, ERISA Litig.*, 258 F. Supp. 2d 576, 598 (S.D. Tex. 2003).

Defendants are high-level officers of Biogen that exercised day-to-day control over the decision-making processes of the Company and were responsible for its public statements (¶¶ 33-38), they were clearly "control persons" under Section 20(a). Thus, Plaintiffs' control person liability claim should be sustained. *Aldridge*, 284 F.3d at 85.[32]

CONCLUSION

For the reasons set forth herein, Plaintiffs respectfully request that the Court deny Defendants' motion to dismiss in its entirety.[33]

Dated: December 22, 2006

MOULTON & GANS, P.C.
By: /s/ Nancy Freeman Gans
Nancy Freeman Gans, BBO # 184540
55 Cleveland Road
Wellesley, MA 02481
Telephone: (781) 235-2246
Facsimile: (781) 239-0353
Liaison Counsel for Plaintiffs

ENTWISTLE & CAPPUCCI LLP
Vincent R. Cappucci
Stephen D. Oestreich
Robert N. Cappucci
Shannon L. Hopkins
280 Park Avenue, 26th Floor West
New York, NY 10017
Telephone: (212) 894-7200
Facsimile: (212) 894-7272

MILBERG WEISS BERSHAD & SCHULMAN LLP
Sanford P. Dumain
Richard Weiss
Ann E. Gittleman
One Pennsylvania Plaza
New York, NY 10119-0165
Telephone: (212) 594-5300
Facsimile: (212) 868-1229

Lead Counsel for Plaintiffs

---

[32] Defendants correctly state that culpable participation is not an element of a Section 20(a) claim in the First Circuit. Defs.' Mem. 30. *See Aldridge*, 284 F.3d at 85. Moreover, whether a defendant is a control person is a question of fact not properly resolved at the pleading stage. *See Cabletron*, 311 F.3d at 41.

[33] If any deficiencies are found by the Court, Plaintiffs respectfully request leave to amend, which should be freely granted. *See, e.g., In re Cytyc Corp. Sec. Litig.*, No. 02-12399-NMB, 2005 U.S. Dist. LEXIS 6166, at *108 (D. Mass Mar. 1, 2005) (The Honorable United States Magistrate Judge M. Bowler).

CERTIFICATE OF SERVICE

I, Nancy Freeman Gans, hereby certify that a true copy of the above document was served upon the attorney of record for each party by ECF.

/s/ Nancy Freeman Gans
Nancy Freeman Gans

EXHIBIT

PARTICULARIZED ALLEGATIONS CONTAINED IN PLAINTIFFS' CONSOLIDATED CLASS ACTION COMPLAINT

(1)[1] Allegations Of "Why" Statements Are False And Misleading	(2) Supporting "Facts" (Citation to Am. Compl.)	(3) Defendants' Claimed Pleading Deficiencies	(4) Plaintiffs Have Sufficiently Alleged Particularized Facts That Satisfy the PSLRA And Rule 9(b)
"Tysabri . . . was an immunosuppressive drug that left patients vulnerable to opportunistic infections" (Am. Compl. ¶ 97)	Research published in 1992 "concluded" that TYSABRI® prevented migration of immune cells to all organs of the body. ¶¶ 98; 64-66)	That research made conclusions only as to immune response in the central nervous system (pp. 13-15)	In Plaintiffs' Memorandum of law in Opposition to Defendants' Revised Motion to Dismiss the Consolidated Class Action Complaint ("Pls.' Mem."), Plaintiffs allege the following particularized facts demonstrating Tysabri is a highly immunosuppressive drug (*See* Pls.' Mem. 20): (1) Defendants' knowledge concerning the inherent nature of the way Tysabri works to turn off the immune system ¶¶ 98-99; [2] (2) Defendants' admissions at the March 2006 FDA Hearing concerning opportunistic infections that occurred during the Tysabri clinical trials ¶¶ 132-40; (3) the majority of the Tysabri clinical trials were unblinded and, thus, Defendants had direct access to the trial results ¶ 95; (4) Defendants' concealment of known opportunistic infections from the FDA prior to its approval of Tysabri ¶¶

[1] Columns (1) through (3) above were taken directly from Exhibit A of Defendants Memorandum. Column (4) contains references to Plaintiffs' opposition to Defendants' claimed pleading defects.

[2] References to "¶__" and "¶¶__" are to paragraphs of the Consolidated Class Action Complaint ("Complaint" or "Compl.").

(1) [1] **Allegations Of "Why" Statements Are False And Misleading**	(2) **Supporting "Facts" (Citation to Am. Compl.)**	(3) **Defendants' Claimed Pleading Deficiencies**	(4) **Plaintiffs Have Sufficiently Alleged Particularized Facts That Satisfy the PSLRA And Rule 9(b)**
			129-51; (5) Defendants had access to medical and scientific journals containing specific warnings of the risks of Tysabri ¶¶ 113-17; (6) Defendants participated in industry conferences where the severe immunosuppressive effects of Tysabri were discussed ¶ 118; (7) Defendants' duties and obligations under the Collaboration Agreement ¶¶ 76-79; (8) Defendants had access to animal study test results warning that Tysabri was highly immunosuppressive ¶¶ 101-12; and (9) numerous confidential sources whose personal accounts corroborated these well-pleaded facts. ¶¶ 143-50.
"animal studies indicated that Tysabri worked to turn off the immune system" (Am. Compl. ¶ 97)	Animal studies conducted by Defendants "confirmed" that TYSABRI® prevented immune response in all organs of the body (¶¶ 101-03)	No particularized allegations of what was observed in animal studies or why those results support Plaintiffs' conclusions. (p. 14)	The Complaint alleges the specific dates (*when*) of animal Studies (*what*) conducted by Biogen and Elan (*who*), which all noted "unexplained deaths," as well as unidentified masses in one study (Biogen Study # 309-010-01) (*where*), which scientists concluded may be the result of severe immunosuppression (*how*). ¶¶ 103-05, 108, 114, 116-17. *See* Pls.' Mem. 15-17.

(1) [1] **Allegations Of "Why" Statements Are False And Misleading**	(2) **Supporting "Facts" (Citation to Am. Compl.)**	(3) **Defendants' Claimed Pleading Deficiencies**	(4) **Plaintiffs Have Sufficiently Alleged Particularized Facts That Satisfy the PSLRA And Rule 9(b)**
"similar warnings were made in publications in scientific and medical journals regarding the severe immunosuppressive effects of Tysabri" (Am. Compl. ¶ 97)	Published studies by academic researchers hypothesized that TYSABRI® may impair immune response (¶¶ 104-17)	At most, those articles discuss only theoretical side effects, and none mention PML (pp. 15-16)	The Complaint alleges that Defendants had access to medical and scientific journals containing specific warnings of the risks of Tysabri. ¶¶ 113-17. Each of these allegations provide specific details of the date of the publication (*when*), author (*who*), source of the article (*where*) and conclusions reached (*what*), including, for example: (1) Warnings that Tysabri "has multiple effects on the immune system and may be problematic in treating established autoimmune diseases such as MS" (¶ 109); and (2) concerns about the "serious risks" that Tysabri posed to patients on the drug because "recipients of the therapy would become generally compromised in their ability to fight infection. This concern has been borne out in a phase 2 trial in MS . . . ." ¶ 106. *See* Pls.' Mem. 15-17.
"scientific meetings were held where top scientists discussed the serious and inherent risks of Tysabri" (Am. Comp. ¶ 97)	Dr. Steinman "warned about the risks of opportunistic infections from Tysabri" at 2 conference (¶ 118)	No particularized allegations that any Defendant attended those meetings or what was discussed (p. 16)	The Complaint alleges specific facts that the co-inventor of Tysabri, Dr. Steinman (*who*), warned about the risks of Tysabri (*what*) at industry conferences held in September 2004 in Venice, Italy and in January 2005 in Montana (*when and where*), which ***senior Biogen executives attended***. ¶ 118 *See* Pls.' Mem. 5, 15-17.
"numerous serious opportunistic infections that had already occurred	(i) During the clinical trials, "at least 60	(i) No allegations of when those infections occurred or	(i) The complaint alleges ***when*** Defendants knew of the opportunistic infections that occurred during the clinical

(1) [1] **Allegations Of "Why" Statements Are False And Misleading**	(2) **Supporting "Facts" (Citation to Am. Compl.)**	(3) **Defendants' Claimed Pleading Deficiencies**	(4) **Plaintiffs Have Sufficiently Alleged Particularized Facts That Satisfy the PSLRA And Rule 9(b)**
in patients participating in Tysabri clinical trials, confirmed prior data indicating how dangerous Tysabri actually is" (Am. Compl. ¶ 97)	opportunistic infections" and numerous malignancies were reported (¶¶ 152-55) (ii) Two "confidential sources" believe that the misdiagnosis of PML in the Crohn's trials was "highly suspicious" (¶¶ 156-58)	if they were even caused by TYSABRI®. Further, malignancies were more common in placebo patients (pp. 16-18) (ii) "Confidential sources" do not describe any knowledge of Defendants, or first hand knowledge of that PML event (p. 18)	trials by providing the date each phase of the trial was completed and further alleges that Defendants were aware of such data by at least the following dates, when the trial results were reported. *See, e.g.*, ¶ 87 (Data from Phase I of the MS trials by 1995); ¶88 (Data from Phase II MS trials presented by September 2001); ¶ 91 (Data from Phase II of Crohn's trials announced on May 23, 2001); ¶ 91 (Data from Phase III ENACT-1 study announced on July 24, 2003); ¶ 92 (Data from Phase III ENACT-2 study announced on January 29, 2004); ¶ 164 (Data from Phase III of MS trials completed by February 18, 2004). *See* Pls.' Mem. 13. (i) Plaintiffs allege that Defendants admitted at the March 2006 FDA Hearing that malignancies, particularly those associated with immunosuppression, were ***more frequent*** in Tysabri patients as a group. ¶¶ 133, 138. (ii) CS 7, a Professor of Neurology with expertise in immunology of the central nervous system and MS and CS 8, a senior scientist at the National Institute of Health specializing in the JC virus, had the expertise to determine whether it was medically plausible to misdiagnose PML with brain cancer. ¶¶ 156-57. *See* Pls.' Mem. 23.
Defendants failed to disclose to the FDA opportunistic infections observed during the TYSABRI® clinical trials. (Am. Compl. ¶ 97, 129)	(i) During the Advisory Committee hearings, Defendants "admitted" that they observed "numerous" opportunistic Infections (¶¶ 132-40)	(i) Only 8 opportunistic infections were observed during all clinical trials, and no particularized allegations that Defendants withheld safety information	(i) Plaintiffs allege that a memo dated November 23, 2004, authored by Dr. Ross concluded that, in reviewing ***the entire Tysabri file***, Dr. Ross did not note any evidence of opportunistic infections prior to approving Tysabri (what). ¶ 130. Defendants, by their own admission, assert that none of the FDA materials, including the medical review approving Tysabri and the Tysabri label and package

(1)[1] **Allegations Of "Why" Statements Are False And Misleading**	(2) **Supporting "Facts" (Citation to Am. Compl.)**	(3) **Defendants' Claimed Pleading Deficiencies**	(4) **Plaintiffs Have Sufficiently Alleged Particularized Facts That Satisfy the PSLRA And Rule 9(b)**
	(ii) Biogen Idec and Elan "communicated regularly pursuant to the Collaboration Agreement (¶¶ 141-24; 68-79) (iii) "Confidential Sources" confirm that opportunistic infections occurred during TYSABRI® clinical trials (¶¶ 143-51)	(pp. 20-22) (ii) No particularized allegations of what information was shared or when (pp. 24-25) (iii) Allegations are vague and non-specific, and do not allege that Defendants withheld safety information (pp. 22-24)	insert, contained any mention of any opportunistic infections (¶129). Defs.' Mem. 22, n. 9. Pls.' Mem. n. 19. (ii) Plaintiffs allege the following particularized facts of "what" information Defendants knew and "when" they knew it: (1) Defendants' obligations under the Collaboration Agreement required them to communicate regularly with Elan about issues concerning Tysabri (¶ 76); (2) Defendants admit that physician/investigators were required to report all adverse events to Biogen (Defs.' Mem. 7); (3) Defendant Mullen admitted that he spoke regularly with Kelly Martin, Elan's CEO, about Tysabri (¶ 141); (4) the majority of the clinical trials were unblinded by January 2004, and thus, Defendants were aware of the results (¶¶ 94-99); and (5) confidential sources (CS 3, CS 4 and CS 5) who were intimately involved in the MS clinical trials, corroborate Defendants' knowledge ¶¶ 117, 144-45. *See* Pls.' Mem. 20-23, n. 10. (iii) Plaintiffs allege specific facts demonstrating that each confidential source had personal knowledge of the facts they allege and were in a position to know those facts. ¶¶ 69-71, 99, 117, 144-45, 147, 156-57. Moreover, each cited source's account is corroborated by independent facts cited in the Complaint, and/or other witnesses' accounts, further supporting the reliability of these witnesses' statements. *See* Pls.' Mem. 17, 22-23.